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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,511	12/22/2000	Douglas G. Clark	VTN-527	1745

7590

06/26/2003

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EXAMINER

SCHWARTZ, JORDAN MARC

ART UNIT

PAPER NUMBER

2873

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,511

Applicant(s)

CLARK ET AL.

Examiner

Jordan M. Schwartz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8,10,11 and 14-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,10,11 and 14-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- ☐ Interview Summary (PTO-413) Paper No(s) _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed September 26, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Specifically, concerning the reference EP-0-357-062, applicant has provided an incomplete copy of the reference. The copy provided has the abstract, the Figures and just page 4, and is missing the rest of the pages of the document. Therefore, this reference has been crossed out and has not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8, 10, 15, 17-18, 21-22 and 25-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Rawlings patent no. 5,120,121 (hereinafter referred to as "Rawlings'121).

Rawlings'121 reads on these claims by disclosing the limitations therein including the following: a contact lens (abstract); comprising one surface having a "base layer" (Figure 4, column 9, line 48, the tint mask underlay or overlay being considered as the "base layer"); the base layer having a clear central zone (Figure 4) and a translucent

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color zone (Figure 4, column 16, line 59 to column 17, line 2 and column 17, line 9). Rawlings'121 further discloses one or more additional color layers (Figures 3 and 5, column 15, line 47, column 16, lines 36-62 with the iris patterning portion of Figure 3 considered as the "additional color layer"); the additional color layer as either a second translucent layer or an opaque layer (column 8, line 16); the additional color layer has a clear central zone and a color layer (Figure 3). So, the mask layer can be considered as the "base layer" which is disclosed as having a clear central zone and a translucent color zone and the colored pattern layer can be considered as the "one or more additional color layer" and it is disclosed as being either translucent or opaque and having a clear central zone and a color zone. Furthermore, since applicant is not disclosing any difference in structure between the "base layer" and the "one or more additional color layers" then the iris patterning portion of Figure 3 can be considered as the either the "base layer" or the "additional color layer" and the tint mask underlay of Figure 4 can be considered as either the "base layer" or the "additional color layer".

In reference to the claimed base layer having a diameter of 10 to about 13 mm, Rawlings'121 discloses the tint mask and the iris simulating pattern both having clear pupil portions and both sized to cover the iris of the wearer (Figures 3 and 4, column 16, line 36 to column 17, line 11). The examiner takes Judicial Notice that it is well known in the art of contact lenses and eye anatomy for the iris of an eye to typically have a diameter in the range of 10 to about 13 mm. Furthermore, applicant on page 4, bottom paragraph of the specification states that the color zone is sized to be that of the wearer's iris, typically 10-13 mm. Therefore, it is believed that the tint mask and/or the

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iris patterning portion of Rawlings'121 (either of which can be considered as the "base layer") will inherently have a diameter in the range of 10 to 13 mm, this being reasonably based upon Rawlings'121 disclosing the tint mask and iris patterning portion sized to cover the iris of the wearer and since it is well known in the art of contact lenses and eye anatomy for the iris of an eye to typically have a diameter in the range of 10 to about 13 mm.

Rawlings'121 further discloses the color zones covering greater than 85 percent of the area of the iris (figure 5, column 6, line 67 to column 7, line 12); greater than "about 90 percent" (column 6, line 30, column 7, line 5). In reference to claim 4, since Rawlings'121 discloses that the colored portions of Figures 1-2 can have a central clear and a translucent color zone (column 8, line 16) then the Figure 2 layer can be considered as the "base layer" and the mask layer can be considered as the "additional color layer" and Rawlings'121 therefore discloses the layers coverage within the claimed percentages (Figures 2 and 4, column 6, line 67 to column 7, line 12).

Rawlings'121 further discloses the base layer comprising shapes of striae (Figure 4) or lines (Figures 1-2 if the colored pattern layer and not the mask layer is considered as the "base layer"); and that multiple layers can be applied to the same surface (column 8, lines 50-59). In reference to claim 15, Rawlings'121 further discloses a clear pre-polymer layer (column 12, lines 5-28) and regardless, since the base layers are being applied to a contact lens surface, the contact lens surface will inherently comprise a pre-polymer layer. Rawlings'121 further discloses that the method can comprise depositing

onto a molding surface the layers (column 7, line 46 to column 8, line 34 and column 11, line 45 to column 15, line 36) and the deposition by pad printing (column 11, line 51-58).

Claims 1, 11, 14-15, 17-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Knapp patent no. 4,720,188 (hereinafter referred to as "Knapp'188).

Knapp'188 reads on these claims by disclosing the limitations therein including the following: a contact lens (abstract); comprising one surface having a "base layer" (column 2, line 54 to column 3, line 2 i.e. the layer having the pattern of dots); the base layer having a clear central zone (column 3, line 26 in that the dot pattern is deposited on the iris section and therefore the central pupil section is a clear central zone) and a translucent color zone (column 2, line 67 and column 3, line 26 in that the dot pattern is deposited on the iris section and is disclosed as translucent). Knapp'188 further discloses one or more additional color layers (column 4, line 5); the additional color layer as either a second translucent layer or an opaque layer (column 2, line 67); the additional color layer has a clear central zone and a color layer (column 3, line 26 in that the dot pattern is deposited on the iris section and therefore the central pupil section is a clear central zone and column 2, line 67 and column 3, line 26 in that the dot pattern is deposited on the iris section and is disclosed as translucent). So, the first printed pattern can be considered as the "base layer" which is disclosed as having a clear central zone and a translucent color zone and the colored pattern layer can be considered as the repeat of the pattern and it is disclosed as being either translucent or opaque and will likewise have a clear central zone and a color zone. Knapp'188 further discloses the layers having a radially gradient density (column 3, lines 9-14); the layers

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comprising shapes of circles (Figure 2). In reference to claim 15, since the patterns i.e. layers are being applied to a contact lens surface, the contact lens surface will inherently comprise a pre-polymer layer.

In reference to the claimed base layer having a diameter of 10 to about 13 mm, Knapp'188 discloses the printed pattern having a clear pupil portion and sized to cover the iris of the wearer (Figure 1, column 2, line 37). The examiner takes Judicial Notice that it is well known in the art of contact lenses and eye anatomy for the iris of an eye to typically have a diameter in the range of 10 to about 13 mm. Furthermore, applicant on page 4, bottom paragraph of the specification states that the color zone is sized to be that of the wearer's iris, typically 10-13 mm. Therefore, it is believed that the printed pattern of Knapp'188 will inherently have a diameter in the range of 10 to 13 mm, this being reasonably based upon Knapp'188 disclosing the printed pattern to cover the iris of the wearer and since it is well known in the art of contact lenses and eye anatomy for the iris of an eye to typically have a diameter in the range of 10 to about 13 mm.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rawlings'121 or Knapp'188.

Rawlings'121 and Knapp'188 disclose as is set forth above but do not specifically disclose the lens comprising one of acquafilcon, etafilcon, genfilcon or lenefilcon (as this claim is understood). However, the examiner takes Judicial Notice that it is well known in the art of contact lenses for such lenses to comprise one or more of the above materials. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the contact lens of Rawlings'121 or Knapp'188 as comprising one of acquafilcon, etafilcon, genfilcon or lenefilcon since such materials are well known in the art of contact lenses as a material used for making contact lenses.

Claims 11, 14, 19-20 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rawlings'121 in view of Knapp'188.

In reference to these claims, Rawlings'121 discloses as is set forth above but discloses the color zones of uniform color and not of radially gradient colors as claimed. Knapp'188 teaches that in colored contact lenses comprising central clear zones and colored zones to simulate the iris that it is desirable to use a radially gradient pattern for the purpose of providing a more natural looking iris (column 3, lines 9-15). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the color zones of Rawlings'121 of radially gradient colors since Knapp'188 teaches that in colored contact lenses comprising central clear zones and colored zones to simulate the iris that it is desirable to use a radially gradient pattern for the purpose of providing a more natural looking iris.

R sponse to Arguments

Applicant's arguments filed April 21, 2003 have been fully considered but they are not persuasive. Specifically, applicant argues that neither Rawlings'121 or Knapp'188 disclose a base layer having a translucent color zone of a diameter of about 10-13 mm and with color throughout the zone. However, applicant is arguing limitations that are not being claimed. Specifically, while applicant is claiming a translucent color zone with a diameter of about 10-13 mm, applicant is not claiming this color zone with color throughout the zone. Therefore, for this reason, as well as the reasoning set forth in the rejections above, the examiner believes that the references are still relevant and that applicant's arguments are not persuasive.

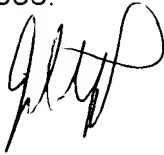
For applicant's additional information, based upon the broadness of the independent claims, almost any colored contact lens that uses two coatings of colorant would read on the independent claims. Specifically, colored contact lens coatings almost all have no colorant in the central pupil region with the colorant sized to cover the iris of the wearer (and would therefore be within the 10-13 mm diameter range). Therefore, any one of the two colored coatings could be considered as the "base layer" and any other coating layer could be considered as the "one or more additional color layers". Furthermore, the colored coatings will inherently include either translucent or opaque colorants.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jordan M. Schwartz whose telephone number is (703) 308-1286. The examiner can normally be reached on Monday to Friday (8:00-5:30), alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Y. Epps can be reached at (703) 308-4883. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and (703) 308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

A handwritten signature in black ink, appearing to read 'J. Schwartz', written in a cursive style.

Jordan M. Schwartz
Primary Examiner
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June 16, 2003